REMARKS

In this Amendment, Applicant has amended Claims 47 – 80 to specify various embodiments of the present invention and overcome the rejection. In addition, the specification has been amended to provide reference to related prior applications. The amendment is editorial in nature. It is respectfully submitted that no new matter has been introduced by the amended claims and specification. All claims are now present for examination and favorable reconsideration is respectfully requested in view of the preceding amendments and the following comments.

OBJECTION TO SPECIFICATION / PRIORITY:

The specification has been objected as failing to include priority information.

It is respectfully submitted that the specification has been amended to include the information on prior related applications. Therefore, objection to the specification is overcome and withdrawal of the objection is respectfully requested.

REJECTIONS UNDER 35 U.S.C. § 102:

Claims 47 – 65 and 69 – 80 have been rejected under 35 U.S.C. § 102 (b) as allegedly being anticipated by Wilson et al. (Immunology, 1972, 23:313-320), hereinafter Wilson. Claims 47 – 65 and 68 – 80 have been rejected under 35 U.S.C. § 102 (b) as allegedly being anticipated by Sheldrake et al. (Immunology, 1985, 56:605-614), hereinafter Sheldrake. Claims 47 – 65 and 69 – 80 have been rejected under 35 U.S.C. § 102 (b) as allegedly being anticipated by Takahashi et al. (J. Dent. Res., 1992, 71:1509-1515), hereinafter Takahashi.

Applicant traverses the rejection and respectfully submits that the present-claimed invention is not anticipated by the cited reference. At first, Claims 47 – 80 have been

amended to further specify that "the milk contains an IgA that is specific to the antigen and has an IgA titre that is between 3 to 18 fold greater than that produced by conducting step (a) alone". The basis of the amendment can be found throughout the specification, especially the examples. It is respectfully submitted that such feature is not disclosed or suggested in Wilson, Sheldrake, or Takahashi. Wilson, Sheldrake, and Takahashi only disclose the milk with an IgA level that is the same as the IgA level from milk obtained in the described step (a) alone, not the specific elevated level as defined in the present application as amended.

In addition, it is respectfully submitted that Wilson describes only total IgA titre levels and not antigen specific IgA titre. The total IgA includes antibodies directed against the immunizing antigen, which means *E. Coli* and other antigens in the Wilson reference. The embodiment of the present invention as defined in amended Claim 47 provides IgA titre in terms of IgA specific to the antigen. It should be appreciated that, due to this difference, it is impossible to conclude that Wilson discloses each and every limitations of the present invention as amended and anticipates Claims 47 – 80. Furthermore, the examples of Wilson only show milk produce by IMM administration and no data is provided to be compared with other modes of administration. As the amended Claim 47 indicated, the milk of the present invention has an IgA titre that is between 3 to 18 fold greater than that produced by conducting step (a) alone. Because Wilson only shows the milk produced by IMM (step (a) alone), it fails to reach the elevated level of IgA of the present invention.

Trials completed by the Applicant indicate that the total IgA titre for the milk of the present invention is as high as 0.75 g/l at approximately day 50 after calving whereas Wilson discloses 0.16 g/l at best.

Sheldrake describes antigen specific to IgA titre. However, the level of IgA in Sheldrake is different from the level of the present invention. The methods described in Sheldrake only use IP/IMM routes of administration, which is only the step (a) of the claim of the present invention. As defined in the present invention, "the IgA has a titre

that is between 3 to 18 fold greater than that produced by conducting step (a) alone." In addition, due to the different antigen used in Sheldrake, it is impossible to conclude that Sheldrake discloses each and every limitations of the present invention as amended and anticipates Claims 47 – 80.

Similar to Sheldrake, Takahashi also only described specific IgA and used a different antigen. Takahashi describes immunization at one site only. As shown in the present invention, IgA titre produced by one injection site is significantly lower than that produced from the method of the instant application. Therefore, it is impossible to conclude that Takahashi discloses each and every limitations of the present invention as amended and anticipates Claims 47 – 80.

Therefore, the newly presented claim is not anticipated by Wilson, Sheldrake, or Takahashi and the rejection under 35 U.S.C. § 102 (b) has been overcome. Accordingly, withdrawal of the rejection under 35 U.S.C. § 102 (b) is respectfully requested.

REJECTIONS UNDER 35 U.S.C. §103:

Claims 47 and 65 – 67 have been rejected under 35 U.S.C. §103 as allegedly being unpatentable over by Wilson in view of Baley et al. (Pediatrics, 1986, 78:225-232), hereinafter Baley. Claims 47 and 65 – 67 have been rejected under 35 U.S.C. §103 as allegedly being unpatentable over by Wilson in view of Cross et al. (J. Am. Vet. Med. Assoc., 1970, 157:1325-1330), hereinafter Cross.

Applicant traverses the rejection and respectfully submits that the embodiments of present-claimed invention are not obvious over the cited prior art references. As indicated above, there are significant differences between the embodiments of the present invention as amended and the disclosures in Wilson, Sheldrake, or Takahashi.

Neither Wilson nor Baley discloses or suggests the elevated level of IgA as defined (3 to 18 folder greater). Although Baley describes that *Candida albicans*

infection occurs in infants, it does not describe the use of milk from a ruminant mammal (regardless of IgA content) to treat the observed fungal infection. Therefore, even if they are combined, they will not render the present invention as amended obvious.

Regarding the combination of Wilson and Cross, it is respectfully submitted that neither Wilson nor Cross discloses or suggests the elevated level of IgA as defined (3 to 18 folder greater). Although Cross describes a treatment using milk from immunized mammary glands as a prophylactic for enteric infections, Wilson and Cross do not refer to a three site immunization and the resulting increase in IgA titre defined in the present invention. Therefore, even if they are combined, they will not render the present invention as amended obvious.

Therefore, the rejection under 35 U.S.C. §103 has been overcome. Accordingly, withdrawal of the rejections under 35 U.S.C. §103 is respectfully requested.

DOUBLE PATENTING

Claims 47 – 80 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 47 – 80 of co-pending U.S. Application No. 10/067,870.

It is respectfully submitted that the present application and the co-pending U.S. Application No. 10/067,870 are commonly owned by the Applicant. Therefore, the rejection has been overcome by the enclosed timely filed terminal disclaimer in compliance with 37 CFR 1.321(c).

Accordingly, withdrawal of the provisional double patenting rejection is respectfully requested.

Having overcome all outstanding grounds of rejection, the application is now in condition for allowance, and prompt action toward that end is respectfully solicited.

Respectfully submitted,

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